UNITED STATES PATENT AND TRADEMARK OFFICE

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EXAMINER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
Office Action Summary	10/696,572	ANDOH ET AL.
	Examiner	Art Unit	
	ERIC S. DEJONG	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2007*.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

    4a) Of the above claim(s) *4,16,29,30 and 32-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-15,17-28 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 November 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED OFFICE ACTION

This application has been transferred to a new examiner.

Applicants response filed 11/16/2007 is acknowledged.

Claims 1-34 are pending. Claims 4, 16, 29, 30, and 32-34 are withdrawn as being

drawn to a non-elected species (see applicants response filed 05/16/2006 and page 2

of the Office action mailed 09/15/2006). Claims 1-3, 5-15, 17-28, and 31 are currently

under examination.

Upon review, a copy of the prior art reference for Hiyama et al. was inadvertently

provided in the previous Office action, mailed 05/17/2007, and further included on the

notice of references cited by the examiner. Included with this Office action is a copy of

the prior art reference of Yang et al., relied upon in the rejection of claims under 35 USC

103(a), and, further, an updated PTO-form 892 with including a corrected citation of

Yang et al.

Claim Objections

The objection to claim 5 because of informalities is withdrawn in view of

amendments made to the instant claim, filed 11/16/2007.

Drawings

The objection to the drawings filed 01/7/2004 is withdrawn in view of the

replacement drawing sheets filed 11/16/2007.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 5-15, 17-28, and 31 are rejected under 35 U.S.C. 101 because the

claimed invention is directed to non-statutory subject matter.

Claims 1-3, 5-15, 17-28, and 31 are drawn to a process and the related system

and computer program for cDNA microarray data correction. The recited process and

related systems, program, and computer readable medium involve the application of

abstract and computational steps for inputting gene expression intensity data,

standardizing gene expression intensity data, estimating distortion depending on a spot

position, performing an S-D transformation, estimating potential distortion, transmitting a

second corrected gene expression intensity data, and outputting said second corrected

gene expression intensity data and, therefore, involves the application of a judicial

exception. Regarding inventions involving the application of a judicial exception, said

application must be a practical application of the judicial exception that includes either a

step of a physical transformation, or produces a useful, concrete, and tangible result

(State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d

1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447

(1999)). In the instant claims, there is no step of physical transformation that results from said application of judicial exception, thus the Examiner must determine if said application of a judicial exception produces a useful, concrete, and tangible result.

A tangible result requires that the claim must set forth a practical application of a judicial exception to produce a real-world result. It is acknowledged that the instant claims recite either an output device for outputting second corrected gene expression intensity data (as in claims 1-3 and 5-12) or a step of outputting second corrected gene expression intensity data, however the instant claims do not further recite any limitation wherein such output is made available to a practitioner of the claimed invention. The generic output as recited in the instant claims encompasses non-statutory embodiments wherein the result (i.e. a second corrected gene expression intensity data) of the instant claims is a signal or directed only to a computer system. See also *In re Nuitjen (2007).* For the benefit of applicants, an amendment to the instant claims to recite that the result (i.e. a second corrected gene expression intensity data) is output to a display or a user would be sufficient to overcome the instant rejection, provided that support for such an amendment is present in the instant specification.

Claim 26 is drawn to a program that is functional descriptive material, *per se.* Regarding data structures representing descriptive material and computer programs, MPEP § 2106.01(I) states:

"Data structures not claimed as embodied in computer-readable media are descriptive material per se and are not statutory because they are not capable of causing functional change in the computer. See, e.g., Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory). Such claimed data structures do not define any structural and functional interrelationships between the data structure and other claimed aspects of the invention which permit the data structure's

functionality to be realized. In contrast, a claimed computer-readable medium encoded with a data structure defines structural and functional interrelationships between the data structure and the computer software and hardware components which permit the data structure's functionality to be realized, and is thus statutory.

  Similarly, computer programs claimed as computer listings per se, i.e., the descriptions or expressions of the programs, are not physical "things." They are neither computer components nor statutory processes, as they are not "acts" being performed. Such claimed computer programs do not define any structural and functional interrelationships between the computer program and other claimed elements of a computer which permit the computer program's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See Lowry, 32 F.3d at 1583-84, 32 USPQ2d at 1035. Accordingly, it is important to distinguish claims that define descriptive material per se from claims that define statutory inventions."

  Since claim 26 is drawn to a program, *per se*, that is not disposed on a physical computer-readable medium, it is not drawn to a non-statutory invention.

  Claim 27 is drawn to a computer-readable memory medium containing an cDNA microarray data correction program. Upon review, the instant specification does not define "computer-readable memory medium" as being limited only to physical media. As such, the computer-readable memory medium as recited in the instant claim encompasses the non-statutory embodiments of signal and carrier waves which are neither tangible nor statutory. See also *In re Nuijten* (2007). As such, claim 27 encompasses non-statutory subject matter.

Claim Rejections - 35 USC § 112

  The rejection of claims 1-3, 5-15, 17-28, and 31 rejected under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention

commensurate in scope with these claims is withdrawn in view of arguments presented

by applicants, filed 11/16/2007.

Claim Rejections - 35 USC § 112, Second Paragraph

Upon further review, the rejection of claim 1 under 35 U.S.C. § 112, second

paragraph, as being indefinite regarding the recitation of the term "previously-adjusted"

is withdrawn.

Upon further review, the rejection of claims 2, 7-8, 10, 14, and 19-20 under 35

U.S.C. § 112, second paragraph, as being indefinite regarding the recitation of the term

"the distortion" is withdrawn.

The rejection of claims 3, 15, 28, and 31 under 35 USC § 112, second

paragraph, for lacking antecedent basis for the recited limitation "the order statistics" is

withdrawn in view of arguments presented by applicants.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly
claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-12, and 23-25 are rejected under 35 U.S.C. 112, second

paragraph, as being indefinite for failing to particularly point out and distinctly claim the

subject matter which applicant regards as the invention.

Independent claim 1 recites a series of means plus function language in the

limitations "a data standardization means for standardizing the gene expression

intensity data" (see lines 8-10 of claim 1), "first correction means for estimating

distortion" (see lines 11-14 of claim 1), "second correction means for performing an SD

transformation" (see lines 15-20 of claim 1). Similarly, Claim 2 recites the limitation of

"S-D transformation means for quantifying the distortion of the gene expression

intensity" (see lines 2 and 3 of claim 2). The recitation of means plus function language

in a claim invokes 35 U.S.C. 112, sixth paragraph in order to determine the metes and

bounds of the claimed invention. Regarding the use of means plus function limitations in

a claim, MPEP §2181(II) states:

> "35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus- function
> language "shall be construed to cover the corresponding structure…described in the specification
> and equivalents thereof." "If one employs means plus function language in a claim, one must set
> forth in the specification an adequate disclosure showing what is meant by that language. If an
> applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly
> point out and distinctly claim the invention as required by the second paragraph of section 112."
> In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc)."

Upon review, the instant disclosure is inadequate as it fails specify any structure

corresponding to the means as recited in the instant claims. It is further noted that the

recent CAFC decision in *Biomedino v. Waters Technology* (Fed. Cir. 2007) held that the

structure of a claimed "means" must be expressly disclosed in the specification even if

one of skill in the art could implement a structure without such a disclosure. Therefore,

the recited "means" causes the metes and bounds of the instant claims to be indefinite

because there is no corresponding disclosure of what structures are specifically

encompassed by said means. Claims 2, 3, and 5-12 are also included under this

rejection due to their dependence from claim 1.

Claim 5 recites the limitation "said data standardization means" in line 2 of said

claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "the correction" in line 3 of said claim. Similarly, claim 12 recites the limitation "the correction" in line 4. Similarly, claim 23 recites the limitation "the correction" in line 3. Similarly, claim 24 recites the limitation "the correction" in line 4. Similarly, claim 25 recites the limitation "the correction" in line 4. Claim 1, from which claims 11 and 12 depend, recites a first and second means for performing corrections (see lines claim 1, lines 11-20). Similarly, claim 13, from which claims 23-25 depend, recites a first and second correction for gene expression data (see claim 13, lines 10-12 and 14-19). This cause the metes and bounds of the instant claims 11, 12, and 23-25 to be indefinite because it unclear which of the two separate and distinct corrections as recited in independent claims 1 and 13 the term "the correction", as recited in dependent claims 11, 12, and 23-25, is intended to refer.

Response to Arguments

Applicant's arguments filed 11/16/2007 have been fully considered but they are not persuasive.

In regards to the previous rejection of claims 11, 24, and 25 under 35 USC 112, second paragraph, as being indefinite regarding the recitation of the term "the correction", applicants argue that the term "the correction" in claim 11 does not represent either the first correction means or the second correction means but rather specifies correction in a whole of the cDNA microarray correction system.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is first noted that the features upon which applicant

relies (i.e., a correction in a whole of the cDNA microarray correction system) are not

recited in the rejected claims. Although the claims are interpreted in light of the

specification, limitations from the specification are not read into the claims. See *In re*

Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is further reiterated

that claim 1, from which claims 11 and 12 depend, recites a first and second means for

performing corrections (see lines claim 1, lines 11-20) and, similarly, claim 13, from

which claims 23-25 depend, recites a first and second correction for gene expression

data (see claim 13, lines 10-12 and 14-19). Since instant claims 11, 12, and 23-25

expressly recite the term "the correction", it is presumed that said term refers back to a

previously recited "correction" from the parent claims. Since the parent claims 1 and 13

each recite two separate and distinct "corrections", it remains unclear from the instant

claims which of the two previously recited corrections the term "the correction", as

recited in claims 11, 12, 23, and 24, is intended to refer.

For the benefit of applicants, if the term "the correction" as recited in claims 11,

12, and 23-25 is intended to specify a correction in a whole of the cDNA microarray

correction system, it is recommended that the instant claims be amended to accurately

and precisely reflect what applicants intend to be the invention.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 2, 6, 13, 14, 26, and 27 under 35 U.S.C. 102(b) as

being anticipated by Yang et al. [Nucleic Acids Research, February 2002, Vol. 30, e15,

10 pages] is withdrawn due to arguments made by applicants on pages 15-18 of the

Remarks of 15 February 2007.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of

the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g)

prior art under 35 U.S.C. 103(a).

Claims 1, 2, 13-14, and 26-27 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Yang et al. (Nucleic Acids Research, 2002, Vol. 30, pages 1-10) in

view of Weng (US PGPUB 2003/0226098).

Claim 1 is drawn a cDNA microarray data correction system for correcting global

an local distortions of microarray data and correcting measurement errors caused by a

difference in sensitivity between fluorescent dyes comprising five steps.

The preamble of claim 1 is taught in the first two sentences of the abstract of

Yang et al. which states:

> There are many sources of systematic variation in cDNA microarray experiments which affect the measured gene expression levels (e.g. differences in labeling efficiency between the two fluorescent dyes). The term normalization refers to the process of removing such variation.

The first step of the body of instant claim 1 states gene expression intensity data

is input and background noise is removed. The passage under "Image processing" in

column 2 of page 2 of Yang et al. states:

> Each hybridization produced a pair of 16-bit images, which were processed using the software package Spot. The main quantities of interest produced by the image analysis methods (segmentation and background correction) are the (R,G) fluorescence intensity pairs for each gene on each array (where R = red for Cy5 and G = green for Cy3). Note that we call the spotted DNA sequences 'genes,' whether they correspond to actual genes, ESTs or DNA sequences from other sources.

The second step of data standardization using grid-by-grid order statistics for

inputting and transmitting gene expression data is described at the top of page 3,

column 1 of Yang et al., which is entitled, "Within-print tip group normalization" and is

based in part on grid data. The model listed is used to input and transmit data.

The third step of instant claim 1 is a first correction means for performing a

distortion depending or a spot position on grid coordinates for the standardized gene

expression intensity data. The "Scale normalization" section in column 1 (line 8) of

page 3 of Yang et al. teaches such a normalization. The equations in this section

illustrate a nonparametric smoothing method.

The fourth step of instant claim 1 is a second correction means for performing a

distortion depending or a spot position on grid coordinates for the standardized gene

expression intensity data. The "Composite normalization" section in column 1 (line 8) of

page 3 of Yang et al. teaches such a second correction means. In addition, the

"Intensity-dependent normalization" at the bottom 10 lines of column 2 of page 2 of

Yang et al. describes the use of MA plots (i.e. output) and could also serve as a second

correction means for the data.

However, the article of Yang et al. does not teach S-D transformations.

The application of Weng, entitled "Methods for analysis of measurement errors in

measured signals" performs second derivative transformations to analyze microarray

data (see paragraphs [0064] to [0070]). The purpose of the application of Weng is

described in paragraph [0010] which states:

> The present invention provides methods for analyzing measurement errors in measured signals obtained in an experiment, e.g.
> measured intensity signals obtained in a microarray gene expression experiment or microarray proteomics experiment.
> Signals from any experimental measurement can be analyzed by the methods of the present invention.

It would be obvious for someone of ordinary skill in the art at the time of the

instant invention to modify the microarray normalization methods of Yang et al. by use

of the microarray signal transformations of Weng because while Yang et al. transforms

and plots the experimental data according to the theories proposed, Weng has the

advantage of using the required S-D (second derivative) transformation for the ability to

better analyze microarray signal data.

Related transformations are plotted in the Figures 1-4 of Weng (the additional

limitation of instant claim 2 is a plot of the S-D transformation).

It would be obvious for someone of ordinary skill in the art at the time of the

instant invention to modify the microarray normalization methods of Yang et al. by use

of the microarray signal transformations of Weng because while Yang et al. transforms

and plots the experimental data according to the theories proposed, Weng has the

advantage of using the required S-D (second derivative) transformation for the ability to

better plot error in microarray signal data.

Instant claim 13 is drawn to a species of instant claim 1 with several intermediate outputting steps after each transformation.

It would have been obvious to someone of ordinary skill in the art to repetitively output results of each intermediate transformation because it is obvious to repeat the steps of a claim. In this instance, instant claim 1 outputs results as a final step. It is obvious to repeat this step of outputting the results at various points in the claim because there is no mandating of the order in which to carry out the steps of instant claim 1. In other words, instant claim 1 can be repeated multiple times with the outputting steps at each of the same locations of the outputting steps in instant claim 13 and make obvious instant claim 13 over the prior art used for instant claim 1.

Related transformations are plotted in the Figures 1-4 of Weng (the additional limitation of instant claim 14 is a plot of the S-D transformation).

It would be obvious for someone of ordinary skill in the art at the time of the instant invention to modify the microarray normalization methods of Yang et al. by use of the microarray signal transformations of Weng because while Yang et al. transforms and plots the experimental data according to the theories proposed, Weng has the advantage of using the required S-D (second derivative) transformation for the ability to better plot microarray signal data error.

Instant claims 26-27 are drawn to the same method steps as instant claim 13 with the additional limitations of claims 26-27 having preambles indicating the method is a DNA microarray data correction program, and a computer readable medium containing the DNA microarray data correction program, respectively.

Weng discloses a computer with computer readable media in Figure 14.

It would be obvious to someone of ordinary skill in the art at the time of the

instant invention to modify Yang et al. in view of the automated method of Weng

because Weng can carry out the method expeditiously and accurately on a computer

system.

Response to Arguments

Applicant's arguments filed 11/16/2007 have been fully considered but they are

not persuasive.

In regard to the rejection of claims under 35 USC 103(a) as being unpatentable

over Yang et al. in view of Weng, applicants argue that the present invention is

completely different from that of Yang et al. in view of using the sum and difference of

gene expression intensities between channels CH1 and CH2. Applicants further cite

page 15, lines 17-20 of the instant specification as support.

In response to applicant's argument that the references fail to show certain

features of applicant's invention, it is noted that the features upon which applicant relies

(i.e., that the invention uses the sum and difference of gene expression intensities

between channels CH1 and CH2) are not recited in the rejected claims. Although the

claims are interpreted in light of the specification, limitations from the specification are

not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed.

Cir. 1993).

Applicants further argue that one of ordinary skill in the art would recognize that no consideration is made at all in Yang et al. about a distortion dependent upon the coordinate positions between grids and that such a distortion dependent on the coordinate position is never corrected in Yang et al.

In response to applicant's arguments against the references individually, it is first noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, it is reiterated that the "Composite normalization" section in column 1 (line 8) of page 3 of Yang et al. teaches such a second reads on the recited means and step for performing a distortion depending or a spot position on grid coordinates for the standardized gene expression intensity data. This section of Yang et al. expressly addresses the normalization of data collected from different print tip groups which read on coordinate positions between grids as instantly claimed. Therefore, the rejection of claims 1, 2, 13-14, and 26-27 under 35 U.S.C. 103(a) as being unpatentable over Yang et al. in view of Weng is maintained.

Applicants further argue that the references do not provide any suggestion or motivation that would lead one skilled in the art to combine Yang et al. and Weng to arrive at the presently claimed invention.

In response, it is noted that in the recent Supreme Court decision in *KSR International Co. v. Teleflex Inc.* expressly rejected the application of a rigid TSM test in determining obviousness. Further, the court ruled that "(t)he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results". In the instant case, one of ordinary skill in the art would recognize that the combination of teachings set forth by Yang et al. and Weng would yield predictable results. Further, applicants have not demonstrated or presented arguments as to why the results produced by the instant claims would be unexpected or unpredictable beyond that which is taught in the prior art. Therefore, the rejection of claims 1, 2, 13-14, and 26-27 under 35 U.S.C. 103(a) as being unpatentable over Yang et al. in view of Weng is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. DEJONG whose telephone number is (571)272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Moran Marjorie can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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